amended herein. The new claims and the amendments introduce no new matter. Support is replete throughout the specification (*e.g.* in claims 1 and 5 as filed, and at page 19, lines 1-28, page 3, lines 20-23, and the like).

35 U.S.C. §112, Second Paragraph.

Claims 1-14, 16-18, 20-26, 71, 79, 82, and 83 were rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite as explained below.

A) "Human ESX nucleic acid".

Claim 1 was rejected under 35 U.S.C. §112, second paragraph, as allegedly vague and indefinite in the recitation of "human ESX nucleic acid". Claim 1 is amended herein to eliminate reference to the term "human ESX nucleic acid thereby obviating this rejection.

B) Antecedent basis for "said label".

Claim 15 was rejected as vague and indefinite because it allegedly lacks antecedent basis for the term "said label". Claim 15 is canceled with entry of this amendment thereby obviating this rejection. It is noted that pending claims 82 and 83 are directed to embodiments where the nucleic acid is labeled with a detectable label and where the detectable label includes a radiolabel, respectively. The cancellation of claim 15 thus does not narrow the scope of the pending claims.

C) Antecedent basis for "murine ESX".

Claim 16 was rejected as vague and indefinite because the phrase "said murine ESX" allegedly lacks antecedent basis. Applicants first note that claim 16 is an independent claim that referred to "**a** murine ESX". Consequently there was no lack of antecedent basis. Nevertheless, claim 16 is amended herein eliminating reference to this phrase and thereby obviating this rejection.

D) The terms "ESX transcription factor", "ESX gene", and "ESX polypeptide".

Claims 71 and 79 were rejected as vague and indefinite because the specification allegedly does not reasonably apprise one of skill in the art what structures are encompassed by the terms "ESX transcription factor", "ESX gene", or "ESX polypeptide". Claim 71 was amended herein to eliminate recitation of these terms thereby obviating this rejection. Claim 79 was amended herein to eliminate reference to the phrase "an ESX nucleic acid". Since claim 79 is not presently being examined

with respect to the polypeptide or to the antibody Applicants submit there is no need at this time to amend the reference to an "ESX polypeptide".

Improper restriction of claim 79.

Claim 79 was objected to because it is allegedly drawn to multiple patentably distinct products. The Examiner required applicants to amend claim 79 to delete references to the polypeptide and antibody products.

Applicants object to the Examiner's requirement and note that such a requirement is improper in light of prevailing case law (*see, e.g., In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978); *In Re Haas* 179 USPQ 623, 624, 625; and *In Re Haas* 198 USPQ 334-337) in which the Federal Circuit has held that:

> As a general proposition, an applicant has a right to have each claim examined on the merits.
>
> * * *
>
> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
>
> * * *
>
> §121 provides the Commissioner with the authority to promulgate rules designed to restrict an application to one of several claimed inventions, ... It does not provide a basis under the authority of the Commissioner to reject a particular claim on that same basis.
>
> * * *
>
> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses. *In Re Weber, supra.*

The objection made by the Examiner is clearly improper and should be withdrawn. Applicants respectfully recommend that if the Examiner wishes to examine claim 79 with respect to the nucleic acid, he should put forth a requirement for an Election of Species.

35 U.S.C. §112, First Paragraph.

A) Description Requirement.

Claims 1, 4-14, 16, 20-26, 71, 79, 82, and 83 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly provided inadequate description to support the claimed genus of polynucleotides. Claims 71 and 79 were also rejected because they were drawn to a transfected cell comprising a heterologous gene encoding an ESX transcription factor, and a kit comprising a container containing an ESX nucleic acid or subsequence thereof, respectively. The Examiner interpreted the terms "ESX transcription factor" and "ESX nucleic acid" to encompass any of the nucleic acid species encompassed by claims 1 or 16 and alleged that the specification does not provide an adequate written description of the genus of nucleic acids encompassed by claims 1 or 16 and therefore does not provide an adequate written description of the claimed cells or kits. Applicants respectfully traverse.

The Examiner is reminded that "[t]he written description requirement **does not require the applicant 'to describe exactly the subject matter claimed**, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. [emphasis added] '" *Union Oil Co. v Atlantic Richfield et al.* 208 F.3d 989 (Fed. Cir. 2000) *citing In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2D (BNA) 1614, 1618 (Fed. Cir. 1989).

In the present case, independent claim 1, 16 are amended herein to recite, respectively:

> 1. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1, and that encodes a transcription factor.
>
> 16. An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:15, and that encodes a transcription factor.

while claims 71 and 79 are amended to refer back to claim 1.

There is simply no question that the specification, as filed, communicates to one of ordinary skill in the art that Applicants invented what is claimed. As stated by the Federal Circuit in *Union Oil:*

> If lack of literal support alone were enough to support a rejection under §112, then the statement of In re Lukach. . . that "the invention claimed does not

> have to be described in ipsis verbis in order to satisfy the description requirement of §112, is empty verbiage.

Thus, literal language describing every claimed species is not required to meet the description requirement. To the contrary, as evidenced in *Union Oil*, guidelines and functional descriptions leading one of skill to the claimed invention are sufficient to meet the description requirements.

In the present case, the specification provides more than guidelines and functional descriptions. Particular reference nucleic acid and amino acid sequences are provided. Stringent hybridization conditions are defined. Numerous sequences meeting the limitations of claims 1 and 16 (and new claims 86-89) readily identified. Consequently, given the level of skill in the art, it is readily apparent that Applicants were in possession of the claimed invention.

Moreover, Applicants note that **the form of claims 1 and 16 has been deemed by the Patent Office to meet the written description guidelines**. In particular, Example 9, provided in the Interim Written Description Guidelines, promulgated by the U.S. Patent Office specifically addresses whether or not a claim similar to that of claims 1 or 16 meets the description requirement. As stated by the Patent Office in their own training materials:

> Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention.

Accordingly the claims, as amended herein meet the Written Description requirement and the rejection of claims 1, 4-14, 16, 20-26, 71, 79, 82, and 83 under 35 U.S.C. §112, first paragraph, should be withdrawn.

B) Rejection of claims 1, 4-6, 8, 89, 82, and 83.

The Examiner rejected claims 1, 4-6, 8, 89, 82, and 83 under 35 U.S.C. §112, first paragraph, alleging that the claimed genus is overbroad. In particular, the Examiner alleged that claim 1 encompasses species of nucleic acid that may be as small as one nucleotide, that the term "human ESX nucleic acid" is not defined structurally and thus the claim is drawn to nucleic acid that hybridizes to an undefined target sequence. In addition the Examiner alleged that the term stringent conditions is not defined by the claim. Applicants respectfully traverse by argument and amendment.

As explained above, claims 1, and 16 are amended herein to eliminate reference to the term "human ESX" nucleic acid. Moreover the claims, as amended, are clear that the nucleic acids encode a transcription factor. Thus the Examiner's comments regarding the length of the claimed nucleic acids and the "human ESX nucleic acid language" are no longer applicable.

With respect to the "stringent hybridization conditions" language, Applicants submit that this term is well known and understood by one of ordinary skill in the art. Moreover, the specification expressly defines such conditions (*see, e.g.,* page 13, line 26 through page 14, line 6). Finally, Applicants note that even the Patent Office has acknowledged that a claim reciting stringent hybridization conditions need not expressly recite the hybridization conditions (*see, e.g.,* Example 9 in the Revised Interim Description Guidelines). In view of the foregoing, Applicants submit that the Examiner's rejection under 35 U.S.C. §112, first paragraph, of claims 1, 4-6, 8, 89, 82, and 83 is no longer applicable and respectfully request that this rejection be withdrawn.

C) Rejection of claims 7, and 10-14.

The Examiner rejected claims 7, and 10-14 as allegedly not meeting the requirements of the description requirement because they allegedly read on nucleic acids encoding a partial protein. Applicants note that, as explained above, independent claims 1 and 16 now are drawn to nucleic acids encoding a transcription factor. Accordingly, dependent claims 7 and 10-14 also read on nucleic acids encoding a transcription factor (not a partial protein). The Examiner's comments thus no longer obtain, and the rejection of claims 7, and 10-14 should be withdrawn.

D) Rejection of claims 16, and 20-26.

Claims 16, and 20-26 were rejected under 35 U.S.C. §112, first paragraph, because, according to the Examiner, they read on any nucleic acid that hybridizes to SEQ ID NO: 15 which is a genomic sequence including non-coding regions. The Examiner also alleged that the sequence of claims 16 and 20-26 has no size limitation. As explained above, independent claims 1 and 16 now are drawn to nucleic acids encoding a transcription factor. This creates, in effect, a size limitation. The Examiner's comments thus no longer obtain, and the rejection of claims 16 and 20-26 should be withdrawn.

E Rejection of claims 71 and 79.

Claims 71 and 79 were rejected in effect, because the Examiner interpreted the terms "ESX transcription factor" and "ESX nucleic acid" to encompass any of the nucleic acid species

encompassed by claims 1 or 16 and alleged that the specification does not provide an adequate written description of the genus of nucleic acids encompassed by claims 1 or 16 and therefore does not provide an adequate written description of the claimed cells or kits.

For the reasons provided above, claims 1 and 16, as amended herein meet the description requirement. Moreover, claims 71 and 79 no longer recite "ESX transcription factor" or "ESX nucleic acid". Accordingly, Applicants believe claims 71 and 79 meet the description requirement and the rejection of these claims under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §102 and §103(a).

Claims 1, 2, 5-14, 20-26, 82, and 83 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Kola *et al.* (U.S. Patent 5,789,200). Claims 1-14, 16-18, 20-26, 71, 79, 82, and 83 were rejected under 35 U.S.C. §103(a) as allegedly obvious in light of Kola *et al.* (U.S. Patent 5,789,200).

Applicants note that Kola *et al.* is cited against the present application as alleged prior art under 35 U.S.C. §102(e)/§103(c). Applicants further note that the effective date of Kola *et al.* is allegedly October 31, 1996, while the prior date of the present application is November 27, 1996, barely four weeks later.

Upon an indication of other wise allowable subject mater, Applicants will provide a Declaration under 37 C.F.R. §1.131 establishing a date of invention prior to the October 31, 1996 date of Kola *et al.* and thereby obviating this reference as effective prior art.

In view of the foregoing, the issuance of an indication of allowable subject matter, is respectfully requested.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 337-7871.

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APPENDIX A

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN 08/978,217 WITH ENTRY OF THIS AMENDMENT

In the claims:

1. (Twice amended) An isolated nucleic acid comprising a nucleic acid **[selected from the group consisting of:]** **that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1, and that encodes a transcription factor.**

[a nucleic acid that specifically hybridizes to a human ESX nucleic acid under stringent conditions; and

a nucleic acid that encodes an amino acid sequence of SEQ ID NO: 2.]

5. Cancelled.

14. Cancelled.

16. (Once amended) An isolated nucleic acid comprising **[a nucleic acid selected from the group consisting of:]**

a nucleic acid that specifically hybridizes **under stringent conditions to a nucleic acid consisting of the cDNA sequence comprising SEQ ID NO:15, and that encodes a transcription factor.[to a murine ESX nucleic acid under stringent conditions, wherein said murine ESX comprises a nucleic acid sequence as set forth in SEQ ID NO: 15; and**

a nucleic acid that encodes an amino acid sequence of SEQ ID NO: 16.]

20. Cancelled.

71. (Once amended) A transfected cell comprising a heterologous **nucleic acid of claim 1.[gene encoding an ESX transcription factor.]**

79. (Once amended) A kit for the detection of a ESX gene or polypeptide, said kit comprising a container containing a molecule selected from the group consisting of, **a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1, [an ESX nucleic acid or subsequence thereof]**, an ESX polypeptide or subsequence thereof, and an anti-ESX antibody.

84. (New) The kit of claim 79, wherein said nucleic acid is labeled with a detectable label.

85. (New) The kit of claim 84, wherein said detectable label is selected from the group consisting of a radiolabel, an enzyme, a colorimetric label, a magnetic bead, a fluorescent label, and a biotin.

86. (New) An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:2.

87. (New) The nucleic acid of claim 86, wherein said nucleic acid comprises a vector.

88. (New) An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:16.

89. (New) The nucleic acid of claim 88, wherein said nucleic acid comprises a vector.

APPENDIX B

CLAIMS PENDING IN USSN 08/978,217 WITH ENTRY OF THIS AMENDMENT

1. (Once amended) An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the sequence of SEQ ID NO:1, and that encodes a transcription factor.

2. (Once amended) The isolated nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence as set forth in SEQ ID NO: 2.

3. (Once amended) The isolated nucleic acid of claim 2, wherein said nucleic acid comprises a nucleotide sequence as set forth in SEQ ID NO: 1.

4. (Once amended) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid having the nucleotide sequence of a nucleic acid amplified from a genomic library using the primer pairs designated by SEQ ID No. 13 and SEQ ID NO. 14.

6. The nucleic acid of claim 1, wherein said nucleic acid further comprises a vector.

7. (Once amended) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes a polypeptide consisting of an amino acid sequence as set forth in SEQ ID NO.: 7.

8. The isolated nucleic acid of claim 1, wherein said nucleotide sequence has a smallest sum probability of less than about 0.5 when compared to a nucleotide sequence as set forth in SEQ ID NO: 6 using a BLASTN algorithm using default parameters.

9. The isolated nucleic acid of claim 8, wherein said smallest sum probability is less than about 0.2.

10. (Once amended) The nucleic acid of claim 1, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence as set forth in SEQ ID NO: 12 or conservative substitutions of said amino acid sequence.

11. The nucleic acid of claim 10, wherein said nucleic acid is free of dideoxynucleotides.

12. The nucleic acid of claim 10, wherein said nucleic acid is single stranded.

13. The nucleic acid of claim 12, wherein said nucleic acid is a sense strand.

16. (Once amended) An isolated nucleic acid comprising a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid consisting of the cDNA sequence comprising SEQ ID NO:15, and that encodes a transcription factor.

17. (Once amended) The nucleic acid of claim 16, wherein said nucleic acid comprises a nucleic acid that encodes an amino acid sequence of amino acids 2 through 371 of SEQ ID NO: 16.

18. (Once amended) The nucleic acid of claim 17, wherein said nucleic acid comprises a nucleotide sequence as set forth in SEQ ID NO: 15.

21. The nucleic acid of claim 16, wherein said nucleic acid further comprises a vector.

22. The nucleic acid of claim 16, wherein said nucleic acid is labeled.

23. The nucleic acid of claim 22, wherein said nucleic acid is free of dideoxynucleotides.

24. The nucleic acid of claim 22, wherein said nucleic acid is single stranded.

25. The nucleic acid of claim 24, wherein said nucleic acid is a sense strand.

26. The isolated nucleic acid of claim 22, wherein said label is a radionuclide.

71. A transfected cell comprising a heterologous nucleic acid of claim 1.

79. A kit for the detection of a ESX gene or polypeptide, said kit comprising a container containing a molecule selected from the group consisting of a nucleic acid that specifically hybridizes under stringent conditions to a nucleic acid of claim 1,an ESX polypeptide or subsequence thereof, and an anti-ESX antibody.

82. The nucleic acid of claim 1, wherein said nucleic acid is labeled with a detectable label.

83. The nucleic acid of claim 82, wherein said detectable label is selected from the group consisting of a radiolabel, an enzyme, a colorimetric label, a magnetic bead, a fluorescent label, and a biotin.

84. (New) The kit of claim 79, wherein said nucleic acid is labeled with a detectable label.

85. (New) The kit of claim 84, wherein said detectable label is selected from the group consisting of a radiolabel, an enzyme, a colorimetric label, a magnetic bead, a fluorescent label, and a biotin.

86. (New) An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:2.

87. (New) The nucleic acid of claim 86, wherein said nucleic acid comprises a vector.

88. (New) An isolated nucleic acid comprising a nucleic acid that encodes a polypeptide consisting of the amino acid sequence of SEQ ID NO:16.

89. (New) The nucleic acid of claim 88, wherein said nucleic acid comprises a vector.